

REMARKS

The Amendments to the Claims

Claims 1-24 and 33-34 are cancelled. Claim 25 has been amended to recite the words "as candidate agents" to link the preamble with the last step of the claimed method. Support for this amendment is found in the last step of the claimed method. Claim 32 has been amended to recite claim "25" instead of claim "21." This corrects a typographical error and eliminates a redundancy between claims 22 and 32. These amendments neither narrow the claim nor add new matter.

The Invention

The applicants have discovered that CDK4 gene expression is directly regulated by *c-MYC*. (Specification, page 6, lines 13-17.) Claims 25-32 are directed to methods for screening test compounds to identify candidate agents that have anti-cancer activity. A cell which has a genetic alteration that dysregulates *c-MYC* expression is contacted with a test compound. (Specification, page 3, lines 19-21.) Activity of CDK4 in the cell is measured. (Specification, page 3, line 21.) A test compound that inhibits activity of CDK4 is identified as a candidate agent with anti-cancer activity. (Specification, page 3, lines 21-22.)

The Rejection of Claims 25 under 35 U.S.C. 112, second paragraph

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, on grounds of insufficient antecedent basis for the recitation "candidate agent." The applicants respectfully traverse. The recitation is "a candidate agent," thus it does not require antecedent basis. However, to expedite prosecution the applicants have amended claim 25 to recite "candidate agents" in the preamble of the claim.

Applicants respectfully request that the rejection of claim 25 under 35 U.S.C. 112, second paragraph, be withdrawn.

The Rejection of Claims 25-32 under 35 U.S.C. 112, first paragraph

Claims 25-32 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not enabling one of skill in the art to make and/or use the invention. The Patent and Trademark Office asserts that it would require undue experimentation for one of skill in the art to practice the invention because of an alleged lack of reasonable correlation between the breadth of the claims and the enablement set forth. In particular, the Patent and Trademark Office complains that applicants have not enabled test compounds that will inhibit CDK4 activity.

MPEP 2164.08 states: "All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims."

Claims 25-32 are directed to methods of screening compounds for anti-cancer activity. The Office Action acknowledges that “[t]he nature of the invention is to screening compounds for anti-cancer activity.” Office Action page 3, 2nd paragraph. Thus, the Office Action acknowledges that the claims are directed to a process, namely, to a method of screening compounds.

However, the Office Action asserts that the applicants are required to “define, guide or exemplify compounds” because the “the claims are broadly drawn to any compound” and are further required to supply information as to which “compound may be identified.” The Office Action further asserts that the “specification does not give any guidance as to structural or functional characteristics the compound must possess, so it will be capable of inhibiting CDK4 activity.” Office Action, page 3, paragraph 2. Such assertions indicate a fundamental misconstruction of the claims as being directed to a specific product rather than to a process for identifying compounds that have anti-cancer activity.

Applicants claim neither the compounds that will inhibit CDK4 activity nor their use. The claims are directed to a process, a method to screen for compounds to identify candidate agents. The process itself identifies the compounds based on function. Any compound can be screened. Some of the compounds used in the screen will not have activity. However, before one performs the screen one need not know the structure of the compound or whether it will be active.

The method only requires *contacting* a cell comprising a genetic alteration that dysregulates c-MYC expression with a test compound and *measuring* CDK4 activity in the cell.

The specification discloses that methods for *measuring* CDK4 enzymatic activity in the cell are known in the art and refers to an exemplary publication, Li J, et al., Biochemistry 2000, 39: 649-657. Specification, page 8, line 29 and page 9, lines 1-2. Thus, a proper focus on the claimed invention as a method to screen compounds to identify candidate agents with anti-cancer activity reveals that the specification provides all that is necessary for one skilled in the art to practice the claimed invention.

Withdrawal of this rejection and a speedy allowance of all pending claims are respectfully requested.

Respectfully submitted,

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APPENDIX 1

Version of Amended Claims With Markings to Show Changes Made

IN THE CLAIMS:

25. (Amended) A method of screening compounds to identify as candidate agents those which have anti-cancer activity, comprising the [step] steps of:

contacting a cell which has a genetic alteration which dysregulates *c-MYC* expression with a test compound;

measuring activity of CDK4 in the cell, wherein a test compound which inhibits activity of CDK4 is identified as a candidate agent with anti-cancer activity.

32. (Amended) The method of claim [21] 25 wherein the cell has a truncating mutation in *APC*.